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Atty. Dkt. No. 029849-0206

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Vaillant and Juteau

Title: ANTIVIRAL  
OLIGONUCLEOTIDES  
TARGETING HBV

Appl. No.: 10/661,088

Filing Date: 09/12/2003

Examiner:

Art Unit: 1614

CERTIFICATE OF MAILING

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Commissioner for Patents  
P.O. Box 1450  
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Sir:

I The USPTO has waived the requirement under 37 CFR 1.98(a)(2)(i) to submit copies of U.S. patents and U.S. patent application publications when citing and submitting an Information Disclosure Statements in a patent application filed after June 30, 2003 and in an international application that has entered the national stage under 37 USC §371 after June 30, 2003. Accordingly, copies of these types of documents are not being supplied in connection with this application. Reference is being made to OG Notice dated August 5, 2003, *Information Disclosure Statements May Be Filed Without Copies of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003.*

Applicants submit herewith on Form PTO/SB/08 a listing of the documents cited by or submitted to the U.S. PTO in related application Serial No. 10/661,403 also filed 09/12/2003. As provided in 37 CFR §1.98(d), copies of the documents are not being provided since they were

previously submitted to the United States Patent & Trademark Office in that application and are on file with the USPTO.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

**RELEVANCE OF EACH DOCUMENT**

The relevance of the foreign-language document is explained in the related application.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even

entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872.

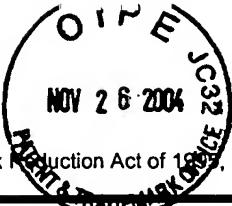
Respectfully submitted,

By 

Date November 23, 2004

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MODIFIED PTO/SB/08 (08-00)

Approved for use through 10/31/2002. OMB 0651-0031

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Substitute for Form 1449B/PTO				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				<b>Application Number</b>	10/661,088
				<b>Filing Date</b>	09/12/2003
				<b>First Named Inventor</b>	Andrew Vaillant et al.
				<b>Group Art Unit</b>	1614
				<b>Examiner Name</b>	
(use as many sheets as necessary)				Attorney Docket Number	029849-0206
Sheet	1	of	13		

## U.S. PATENT DOCUMENTS

## FOREIGN PATENT DOCUMENTS

## **NON PATENT LITERATURE DOCUMENTS**

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	A2	AGRAWAL and KANDIMALLA, "Antisense and/or Immunostimulatory Oligonucleotide Therapeutics," <i>Current Cancer Drug Targets</i> 1:197-209 (2001)		
	A3	ALLEN and CHONN, "Large Unilamellar Liposomes with Low Uptake into the Reticuloendothelial System," <i>FEBS Letters</i> 223(1):42-46 (1987)		
	A4	ARCHAMBAULT, <i>et al.</i> , "Phosphorothioate oligonucleotides inhibit the replication of lentiviruses and type D retroviruses, but not that of type C retroviruses," <i>Arch Virol</i> 139:97-109 (1994)		

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	A5	BERKOW, et al., "Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)," <i>The Merck Manual of Diagnosis and Therapy</i> , 15 <sup>th</sup> ed., 2499-2506 and 46-49 (1987)	
	A6	BLUME and CEVC, "Liposomes for the sustained drug release in vivo," <i>Biochimica et Biophysica Acta</i> 1029:91-97 (1990)	
	A7	BRUNTON, "Section VI Drugs Affecting Gastrointestinal Function," <i>The Pharmacological Basis of Therapeutics</i> 9(38):934-935 (1996)	
	A8	BUUR, et al., "Penetration of 5-Fluorouracil and Prodrugs Across the Intestine of the Albino Rabbit: Evidence for Shift in Absorption Site from the Upper to the Lower Region of the Gastrointestinal Tract by Prodrugs," <i>Journ. of Controlled Release</i> 14:43-51 (1990)	
	A9	CAMPBELL and REIN, "In Vitro Assembly Properties of Human Immunodeficiency Virus Type 1 Gag Protein Lacking the p6 Domain," <i>Journ. of Virol.</i> 73:2270-2279 (1999)	
	A10	CEVC, et al., "Ultraflexible vesicles, Transfersomes, have an extremely low pore penetration resistance and transport therapeutic amounts of insulin across the intact mammalian skin," <i>Biochimica et Biophysica Acta</i> 1368:201-215 (1998)	
	A11	CHENG, et al., "Interactions Between Single-Stranded DNA Binding Protein and Oligonucleotide Analogs with Different Backbone Chemistries," <i>Journ. Mol. Recognition</i> 10:101-107 (1997)	
	A12	CONSTANTINIDES, et al., "Formulation and Intestinal Absorption Enhancement Evaluation of Water-in-Oil Microemulsions Incorporating Medium-Chain Glycerides," <i>Pharmaceutical Res.</i> 11:1385-1390 (1994)	
	A13	CROOKE, et al., "Pharmacokinetic Properties of Several Novel Oligonucleotide Analogs in mice," <i>Journ. Pharm. and Experim. Therap.</i> 277(2):923-937 (1996)	
	A14	CROOKE, S., "Progress in Antisense Technology: The End of the Beginning," <i>Meth. in Enzym.</i> 313:3-45 (1999)	

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Sheet	3	of	13		

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	A15	Du PLESSIS, et al., "Topical Delivery of Liposomally Encapsulated Gamma-Interferon," <i>Antivir. Res.</i> 18:259-265 (1992)	
	A16	EL-HARIRI, et al., "The Mitigating Effects of Phosphatidylcholines on Bile Salt- and Lysophosphatidylcholine-induced Membrane Damage," <i>J. Pharm. Pharmacol.</i> 44:651-654 (1992)	
	A17	ENGLISCH and GAUSS, "Chemically Modified Oligonucleotides as Probes and Inhibitors," <i>Angewandte Chemie</i> 30(6):613-722 (1991)	
	A18	FENG, et al., "Reversible Binding of Recombinant Human Immunodeficiency Virus Type 1 Gag Protein to Nucleic Acids in Virus-Like Particle Assembly In Vitro," <i>Journ. of Virol.</i> 76(22):11757-11762 (2002)	
	A19	FENNEWALD, et al., "Inhibition of herpes simplex virus in culture by oligonucleotides composed entirely of deoxyguanosine and thymidine," <i>Antiviral Res.</i> 26:37-54 (1995)	
	A20	GABIZON, et al., "Liposome formulations with prolonged circulation time in blood and enhanced uptake by tumors," <i>Proc. Natl. Acad. Sci. USA</i> 85:6949-6953 (1988)	
	A21	GOA, et al., "Effect of Phosphorothioate Homo-oligodeoxynucleotides on Herpes Simplex Virus Type 2-induced DNA Polymerase," <i>Journ. of Biol. Chem.</i> 264(19):11521-11526 (1989)	
	A22	GAO, et al., "Inhibition of Herpes Simplex Virus Type 2 Growth by Phosphorothioate Oligodeoxynucleotides," <i>Antimicrobial Agents and Chemotherapy</i> 34(5):808-812 (1990)	

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	A23	HIGUCHI, et al., "Particle Phenomena and Course Dispersions," <i>Remington's Pharmaceutical Sciences</i> 21:301-329 (1985)	
	A24	HO, et al., "Preparation of Microemulsions Using Polyglycerol Fatty Acid Esters as Surfactant for the Delivery of Protein Drugs," <i>Journ. of Pharm. Sci.</i> 85:138-143 (1996)	
	A25	HU, et al., "Topical delivery of cyclosporine A from non-ionic liposomal systems: an <i>in vivo/in vitro</i> correlation study using hairless mouse skin," <i>S.T.P. Pharma Sciences</i> 4(6):466-469 (1994)	
	A26	ILLUM and DAVIS, "The organ uptake of intravenously administered colloidal particles can be altered using a non-ionic surfactant (Poloxamer 338)," <i>FEBS</i> 1212 167:79-82 (1984)	
	A27	INAGAWA, et al., "Inhibition of human immunodeficiency virus type 1 replication by P-stereodefined oligo (nucleoside phosphorothioate)s in a long-term infection model," <i>FEBS Lett.</i> 528:48-52 (2002)	
	A28	JAIRATH, et al., "Inhibition of respiratory syncytial virus replication by antisense oligodeoxyribonucleotides," <i>Antiviral Res.</i> 33:201-213 (1997)	
	A29	JARRETT, H., "Affinity chromatography with nucleic acid polymers," <i>J. Chromatography</i> 618:315-339 (1993)	
	A30	KABANOV, et al., "A new class of antivirals: antisense oligonucleotides combined with a hydrophobic substituent effectively inhibit influenza virus reproduction and synthesis of virus-specific proteins in MDCK cells," <i>FEBS Lett.</i> 259:327-330 (1990)	

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	A31	KANDIMALLA, et al., "Effects of Phosphorothioate Oligodeoxyribonucleotide and Oligoribonucleotides on Human Complement and Coagulation," <i>Bioorg. &amp; Med. Chem. Lett.</i> 8:2103-2108 (1998)	
	A32	KEAN, et al., "Inhibition of Herpes Simplex Virus Replication by Antisense Oligo-2'-0-methylribonucleoside Methylphosphonates," <i>Biochemistry</i> 34:14617-14620 (1995)	
	A33	KLIBANOV, et al., "Amphipathic polyethyleneglycols effectively prolong the circulation time of liposomes," <i>FEBS Lett.</i> 268:235-237 (1990)	
	A34	KLIMUK, et al., "Enhanced Anti-Inflammatory Activity of a Liposomal Intercellular Adhesion Molecule-1 Antisense Oligodeoxynucleotide in an Acute Model of Contact Hypersensitivity," <i>Journ. of Pharm. &amp; Exper. Ther.</i> 292:480-488 (2000)	
	A35	KOOL, E., "Replacing the Nucleobases in DNA with Designer Molecules," <i>Acc. Chem. Res.</i> 35:936-943 (2002)	
	A36	LAVIGNE et al., "Is antisense an appropriate nomenclature od design for oligodeoxynucleotides aimed at the inhibition of HIV-1 replication?" <i>AAPS PharmSci</i> , 4:1-11, 2002	
	A37	LEBEDEVA and STEIN, "Antisense Oligonucleotides: Promise and Reality," <i>Annu. Rev. Pharmacol. Toxicol.</i> 41:403-419 (2001)	
	A38	LEE, et al., "Mucosal Penetration Enhancers For Facilitation of Peptide and Protein Drug Absorption," <i>Crit. Rev. in Ther. Drug Carrier Syst.</i> 8(2):91-192 (1991)	

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	A39	LERNER, et al., "A Six-Month Trial of Valacyclovir in the Epstein-Barr Virus Subset of Chronic Fatigue Syndrome: Improvement in Left Ventricular Function," <i>Drugs of Today</i> 38(8): 549-561 (2002)			
	A40	LETSINGER, et al., "Cholesteryl-conjugated oligonucleotides: Synthesis, properties, and activity as inhibitors of replication of human immunodeficiency virus in cell culture," <i>Proc. Natl. Acad. Sci. USA</i> 86:6553-6556 (1989)			
	A41	MANOHARAN, et al., "Chemical Modifications to Improve Uptake and Bioavailability of Antisense Oligonucleotides," <i>Ann. N.Y. Acad. Sci.</i> 660:306-309 (1992)			
	A42	MANOHARAN, et al., "Introduction of a Lipophilic Thioether Tether in the Minor Groove of Nucleic Acids for Antisense Applications," <i>Bioorg. &amp; Med. Chem. Letters</i> 3:2765-2770 (1993)			
	A43	MANOHARAN, et al., "Cholic Acid-Oligonucleotide Conjugates for Antisense Applications," <i>Bioorg. &amp; Med. Chem. Lett.</i> 4:1053-1060 (1994)			
	A44	MANOHARAN, et al., "Oligonucleotide Conjugates: Alteration of the Pharmacokinetic Properties of Antisense Agents," <i>Nucleosides &amp; Nucleotides</i> 14(3-5):969-973 (1995)			
	A45	MANOHARAN, et al., "Lipidic Nucleic Acids," <i>Tetrahedron Lett.</i> 36:3651-3654 (1995)			
	A46	MARSHALL, et al., "Inhibition of human immunodeficiency virus activity by phosphorodithioate oligodeoxycytidine," <i>Proc. Natl. Acad. Sci. USA</i> 89:6265-6269 (1992)			

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	A48	MATSUKURA et al., "Antisense phosphorothioates as antivirals against human immunodeficiency virus (HIV) and hepatitis B virus (HBV)." <i>Toxicology Letters</i> , 82/83: 435-538, 1995.	
	A49	MATSUKURA, et al., "Phosphorothioate Analogs of Oligodeoxynucleotides: Inhibitors of Replication and Cytopathic Effects of Human Immunodeficiency Virus," <i>Proc. Natl. Acad. of Sciences of USA</i> 84:7706-7710 (1987)	
	A50	MISHRA, et al., "Improved leishmanicidal effect of phosphorothioate antisense oligonucleotides by LDL-mediated delivery," <i>Biochimica et Biophysica Acta</i> 1264:229-237 (1995)	
	A51	MIYANO-KUROSAKI et al., "Inhibition of HTLV-I induction and virus-induced syncytia formation by oligodeoxynucleotides." <i>Virus Genes</i> , 12:205-217, 1996.	
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				<b>Filing Date</b>	09/12/2003
				<b>First Named Inventor</b>	Andrew Vaillant et al.
				<b>Group Art Unit</b>	1614
				<b>Examiner Name</b>	
(use as many sheets as necessary)				<b>Attorney Docket Number</b>	029849-0206
Sheet	8	of	13		

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	A55	MURANISHI, S., "Absorption Enhancers," <i>Crit. Rev. in Ther. Drug Carr. Syst.</i> 7:1-33 (1990)	
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	A57	NEURATH, et al., "Anti-HIV-1 activity of anionic polymers: a comparative study of candidate microbicides," <i>BMC Infectious Diseases</i> 2:1-11 (2002)	
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	A60	ORUM and WENGEL, "Locked nucleic acids: A promising molecular family for gene-function analysis and antisense drug development," <i>Curr. Op. in Molecular Ther.</i> 3:239-243 (2001)	
	A61	PAN et al., "Isolation of virus-neutralizing RNAs from a large pool of random sequences." <i>Proc. Nat. Acad. Sci. USA</i> , 92:11509-11513, 195.	
	A62	PAPAHADJOPoulos, et al., "Targeting of Liposomes to Tumor Cells <i>in Vivo</i> ," <i>Ann. N.Y. Acad. Sci.</i> pp. 64-74 (1987)	

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Sheet	9	of	13		

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Sheet	10	of	13		

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Sheet	11	of	13		

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Sheet	12	of	13		

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	A90	YAMAMOTO, et al., "A Mechanistic Study on Enhancement of Rectal Permeability to Insulin in the Albino Rabbit," <i>Journ. of Pharm. and Exp. Ther.</i> 263:25-31 (1992)	
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	A95	ZHOU and HUANG, "Targeted delivery of DNA by liposomes and polymers," <i>Journ. of Controlled Release</i> 19:269-274 (1992)	
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